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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,148	02/20/2004	Craig M. Ruecker	2997-19-1	5350

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EXAMINER

DAVIS, RUTH A

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,148

Applicant(s)

RUECKER ET AL.

Examiner

Ruth A. Davis

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-37 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37, 47-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed on September 1, 2006 have been received and entered into the case. Claims 1-4,8,10-12,14-15,18-21,23-25 are canceled; claims 47-57 are added; claims 35-37 and 47 – 57 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim 57 is objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 112

1. Rejections under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 35 – 37, 47, 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudin et al. (US 5179012) in view of Wagner et al. (US 4720456).

Applicant claims a process for obtaining lipids from a microorganism, the method comprising (a) growing the microorganism in a fermentation medium, (b) contacting the medium with a base, (c) increasing the temperature to at least about 50C to lyse the cells, (d) separating substances with different densities to produce a phase separated mixture with a heavy and light layer, (e) removing the heavy layer, (f) adding a washing solution to light layer, (g) separating substances with different densities from the mixture, (h) removing a heavy layer from the second phase separated mixture, (i) repeating steps (f) – (h) until the lipid becomes substantially non-emulsified. The aqueous solution of (d) comprises solid material; the microorganism is algal, fungi, bacteria, or protist; and step (b) is conducted without drying the microorganisms.

Gudin teaches methods for obtaining liposoluble components from microorganisms, specifically, microalgae, the method comprising culturing the microorganism in a medium, grinding the organism and separating the phases via centrifugation in order obtain the desired components (abstract, col.2,4). The phases, or layers, are separated (col.2 line 37-55) into two phases: a lipid solution and an aqueous solution containing cellular residues (or solid cell material) wherein the treatment (or separation) is carried out via centrifuging (col.4 line 11-20).

Gudin does not teach the method wherein the fermentation medium is contacted with a base, or wherein the temperatures are raised to at least 50C. However, Wagner teaches methods for obtaining liposoluble components from microorganisms wherein the culture medium is adjusted with alkaline metal hydroxides and cultured at temperatures of 50C (col.4,5). Wagner teaches the addition of hydroxide increases yield of lipids (col.5). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to culture microorganisms at about 50C in the presence of hydroxides for the disclosed advantages of increased lipid yields. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to add bases to the culture mediums of microorganisms with a reasonable expectation for successfully obtaining lipids and liposoluble components. Although the references do not specifically teach multiple separation of the phases, it would have been well within the purview of one in the art to optimize the number of washings and separations as a matter of routine experimentation. Thus, one of ordinary skill in the art would have had a reasonable expectation for successfully obtaining lipids.

5. Claims 35 – 37 and 47 – 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudin in view of Wagner and Barclay (US 5130242).

Applicant claims a process for obtaining lipids from a microorganism, the method comprising (a) growing the microorganism in a fermentation medium, (b) contacting the medium with a base, (c) increasing the temperature to at least about 50C to lyse the cells, (d) separating substances with different densities to produce a phase separated mixture with a heavy and light layer, (e) removing the heavy layer, (f) adding a washing solution to light layer, (g) separating

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substances with different densities from the mixture, (h) removing a heavy layer from the second phase separated mixture, (i) repeating steps (f) – (h) until the lipid becomes substantially non-emulsified. The aqueous solution of (d) comprises solid material; the microorganism can grow at particular salinity levels; are selected from algae, fungi, bacteria, or protist; specifically, from the order Thraustochytriales, genus Thraustochytrium, Schizochytrium or mixtures thereof. More specifically, they are selected from microorganism with identifying characteristics of ATCC 20888, 20889, 20890, 20891, 20892, mutants thereof or combinations thereof. The microorganism is capable of growth at salinity levels of less than about 12 g/L of sodium chloride, capable of producing at least about 0.1 g/L/hour of docosahexaenoic acid (DHA) and comprises at least about 30% by weight of lipid, wherein at least about 30% of said lipid is DHA. Finally, step (b) is conducted without drying the microorganisms.

Gudin teaches methods for obtaining liposoluble components from microorganisms, specifically, microalgae, the method comprising culturing the microorganism in a medium, grinding the organism and separating the phases via centrifugation in order obtain the desired components (abstract, col.2,4). The phases, or layers, are separated (col.2 line 37-55) into two phases: a lipid solution and an aqueous solution containing cellular residues (or solid cell material) wherein the treatment (or separation) is carried out via centrifuging (col.4 line 11-20).

Gudin does not teach the method wherein the fermentation medium is contacted with a base, or wherein the temperatures are raised to at least 50C. However, Wagner teaches methods for obtaining liposoluble components from microorganisms wherein the culture medium is adjusted with alkaline metal hydroxides and cultured at temperatures of 50C (col.4,5). Wagner teaches the addition of hydroxide increases yield of lipids (col.5). At the time of the claimed

invention, it would have been obvious to one of ordinary skill in the art to culture microorganisms at about 50C in the presence of hydroxides for the disclosed advantages of increased lipid yields. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to add bases to the culture mediums of microorganisms with a reasonable expectation for successfully obtaining lipids and liposoluble components. Although the references do not specifically teach multiple separation of the phases, it would have been well within the purview of one in the art to optimize the number of washings and separations as a matter of routine experimentation. Thus, one of ordinary skill in the art would have had a reasonable expectation for successfully obtaining lipids.

Gudin does not teach the process wherein the microalgae are from the order Thraustochytriales, genera Thraustochytrium, Schizochytrium, mixtures thereof, or microorganisms with identifying characteristics of ATCC 20888, 20889, 20890, 20891, 20892, mutants and/or combinations thereof. However, at the time of the invention, one of ordinary skill in the art would have been motivated to use the claimed microorganisms because Barclay teaches a process for the production of microbial products with high concentration of omega 3 highly unsaturated fatty acids, or omega-3 HUFAs, (lipids) using microorganisms or the order Thraustochytriales (abstract). Specifically, Barclay teaches the process wherein Thraustochytrium, Schizochytrium or mixtures thereof are cultured to produce high concentrations of omega-3 HUFAs (col.5 line 20-35). In addition, microorganisms with identifying characteristics of ATCC 20888, 20889, 20890, 20891, 20892 and mutants therefrom are utilized (col.5 line 45-50). Barclay teaches that such microorganisms are fermented with grain to produce the desired omega-3 HUFAs (col.8 line 50-60).

The above references do not specifically teach the process wherein the microorganism comprises at least about 30% by weight of the lipid, are capable of producing at least about 0.1 g/L/hour of docosahexaenoic acid (DHA), wherein at least about 30% of the lipid is DHA or wherein the microorganism is capable of growth at salinity levels of less than about 12 g/L of sodium chloride. However, Barclay does teach desirable characteristics of microorganisms include high content of omega-3 HUFAs and that they are euryhaline, or able to grow in a wide range of salinity, especially a low salinity (col.6 line 42-54). In addition, Barclay names omega-3 HUFAs to include docosahexaenoic acid, of DHA (col.6 line 12-38). At the time of the invention, one of ordinary skill in the art would have been motivated by Barclay to utilize a microorganism with the instantly claimed characteristics because Barclay teaches such characteristics are economically desirable for the production of omega-3 HUFAs (col.6 line 43-47). Furthermore, at the time of the invention, one of ordinary skill in the art would have been able to recognize that optimizations of such characteristics would be desirable in a process for obtaining lipids, as demonstrated and suggested by Barclay.

Response to Arguments

Applicant argues that Gudín does not teach the method separates a light and heavy layer wherein the light layer contains lipids, but teaches only solid/liquid layers. Applicant argues that Wagner does not cure the deficiencies of Gudín; teaches adding bases to dissolve proteins, not to obtain lipids; and does not teach the temperature.

However, these arguments fail to persuade because Gudín specifically teaches the process wherein the phases are separated into multiple layers. Gudín teaches the layers may be separated into 2 or 3 layers whereby the lipid can be purified therefrom (col.4 line 10-30). While Gudín may not expressly teach the lipids are emulsified, the steps are the same, thus the lipids must also be present in the phase separated layer.

Regarding Wagner, the reference specifically teaches adding a base to the culture broth when obtaining lipids from the microorganisms (col.5 line 48-54). While the reference may not specifically disclose the base dissolves proteins, such an action is intrinsic to the method since the method steps are the same. Regarding applicant's assertion that Wagner is recovering proteins, it is reiterated that Wagner specifically identifies adding a base to increase the recovery of lipids (col.5 line 48-54). Finally, regarding the temperature, the claims recite at least about 50C, thus the reference teaches the limitation of at least about 50.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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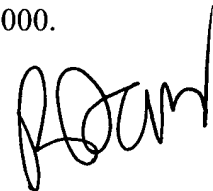
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
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November 24, 2006